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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,022	01/23/2006	Bror Morein	67185-78227	5079
26288 7590 03/12/2007 ALBIHNS STOCKHOLM AB BOX 5581, LINNEGATAN 2 SE-114 85 STOCKHOLM; SWEDEN STOCKHOLM, SWEDEN			EXAMINER CHEN, CATHERYNE	
			ART UNIT	PAPER NUMBER
			1655	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/12/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

10/520,022

**Applicant(s)**

MOREIN ET AL.

**Examiner**

Catheryne Chen

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-14 is/are rejected.
- 7) ☒ Claim(s) 2-5, 13 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date Feb. 2, 06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

Art Unit: 1655

### **DETAILED ACTION**

Currently, Claims 1-14 are pending. Claims 1-5, 10-14 are examined on the merits.

#### ***Election/Restrictions***

Claims 6-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Jan. 31, 2007.

Applicant's election with traverse of Group I (claims 1-5, 10-14) in the reply filed on Jan. 31, 2007 is acknowledged. The traversal is on the ground(s) that it would not be unduly burdensome to examine all of the claims. This is not found persuasive because a search of one group is not coextensive with the search of the other groups. Thus, it would be burdensome to search the entire claims.

The requirement is still deemed proper and is therefore made FINAL.

#### ***Claim Objections***

Claim 2 is objected to because of the following informalities:

In Claim 2, the word iscom is misspelled.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1655

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. What are the fractions of A, B, and C? What is Quil 1-21? Clarification is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Nord (Carbohydrate Research, 2000, 329: 817-829).

Applicant's claim is drawn to a composition of at least two iscom complexes from Quillaja saponaria Molina, Quil 1-21.

Nord teaches saponins from the bark of the Quillaja saponaria Molina tree used as adjuvants with vaccines (Introduction).

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by De Vries et al. (US 4900549).

Applicant's claim is drawn to a composition of at least two iscom complexes from Quillaja saponaria Molina.

Art Unit: 1655

De Vries et al. teaches saponin extract from *Quillaja saponaria* Molina in Quil A (column 8, lines 26-30).

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by MacFarlan et al. (WO98/36772).

Applicant's claim is drawn to a composition of at least two iscom complexes from *Quillaja saponaria* Molina.

MacFarlan et al. teaches saponin from *Quillaja saponaria* (column 35, lines 27-30).

Claims 1-5, 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (WO96/11711).

Applicant's claim is drawn to a composition of at least two iscom complexes from *Quillaja saponaria* Molina, fractions A, B, C, 50 to 70% by weight of fraction A, from 30-70% by weight of fraction C.

Cox et al. teaches saponin preparation of saponins of *Quillaja saponaria* from 50 to 90% by weight of Fraction A and from 50 to 10% by weight of Fraction C, 50 to 70% by weight of fraction A and from 50 to 30% by weight of fraction C, about 70% by weight of fraction A, about 30% by weight of fraction C (claims 1-3), fractions A, B, and C (page 7, line 24).

Claims 1-5, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensil et al. (EP 0362279 B1).

Art Unit: 1655

Applicant's claim is drawn to a composition of at least two iscom complexes from Quillaja saponaria Molina, Quil 1-21.

Kensil et al. teaches Quillaja saponin preparation separated to at least 22 peaks (page 6, lines 47-52).

Claims 1-5, 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (US 6352697 B1).

Cox et al. teaches a saponin vaccine preparation comprising Quillaja saponaria from 50% to 70% by weight of Fraction A of Quil A and from 50% to 30% by weight of Fraction C of Quil A (column 14, lines 26-38, column 16, lines 9-14).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (WO96/11711).

Applicant's claim is drawn to a composition of at least two iscom complexes from Quillaja saponaria Molina, fractions A, B, C, 50 to 70% by weight of fraction A, from 30-70% by weight of fraction C.

Cox et al. teaches saponin preparation of saponins of Quillaja saponaria from 50 to 90% by weight of Fraction A and from 50 to 10% by weight of Fraction C, 50 to 70% by weight of fraction A and from 50 to 30% by weight of fraction C, about 70% by weight of fraction A, about 30% by weight of fraction C (claims 1-3), fractions A, B, and C (page 7, line 24). However, it does not teach the specific percentage weight claimed.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

***Conclusion***


No claim is allowed.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
2-27-07  
SUSAN COE HOFFMAN  
PRIMARY EXAMINER

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Art Unit 1655